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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,909	07/21/2003	Eileen Tozer	D1410-2US	7087
29062 7590 01/24/2008 VERENIUM CORPORATION 4955 DIRECTORS PLACE SAN DIEGO, CA 92121			EXAMINER BERTAGNA, ANGELA MARIE	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,909

Applicant(s)

TOZER ET AL.

Examiner

Angela Bertagna

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☒ Claim(s) 189 is/are allowed.
- 6) ☒ Claim(s) 1, 14, 15, 29, 33, 35, 40, 43-45, 48, 49, 87, 188, 192, 203-205, 217, 218 and 225-228 is/are rejected.
- 7) ☒ Claim(s) 192, 206, 207 and 225 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,14,15,29,33,35,40,42-45,48,49,51,54,56,58,87,106,107,111,113,116,138,143,174,175,177,182,184,187-190,192,203-208 and 215-231.
Continuation of Disposition of Claims: Claims withdrawn from consideration are
42,51,54,56,58,106,107,111,113,116,138,143,174,175,177,182,184,187,190,208,215,216,219-224 and 229-231.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 7, 2007 has been entered.

Status of the Claims

2. Claims 1, 14, 15, 29, 33, 35, 40, 42-45, 48, 49, 51, 54, 56, 58, 87, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187-190, 192, 203-208, and 215-231 are currently pending. Claims 42, 51, 54, 56, 58, 106, 107, 111, 113, 116, 138, 143, 174, 175, 177, 182, 184, 187, 190, 208, 215, 216, 219-224, and 229-231 are withdrawn from consideration as being drawn to a non-elected invention.

Claim Objections

3. Claim 192 is objected to because of the following informalities: This claim makes reference to Figure 15. As noted in section 2173.05(s) of the MPEP, "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table 'is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for

applicant's convenience.' Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993)."

Claim 225 is objected to because of the following informalities:

(A) This claim depends from a withdrawn claim (claim 138).

(B) The status identifier for this claim is incorrect. It should be "previously presented".

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 1st paragraph (Written Description)

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 14, 15, 29, 33, 35, 40, 43-45, 48, 49, 87, 188, 192, 203-205, 217, 218, and 225-228 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The MPEP states, "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1996 (Fed. Cir. 1997)."

In the instant case, independent claims 1, 33, and 188 are drawn to an isolated, synthetic, or recombinant nucleic acid that encodes a fluorescent protein and has at least 75% sequence identity to SEQ ID NO: 29.” Claims 203-207 further limit the required percentage of identity to at least 80%, at least 85%, at least 90%, at least 95%, and at least 98%, respectively. Claim 29 also limits the percent identity to at least 90%. SEQ ID NO: 29 is 687 nucleotides in length. There are approximately 3.22×10^{248} different nucleic acid sequences with 75% identity to the instant SEQ ID NO: 29. Also, there are approximately 2.97×10^{127} different nucleic acids with 90% identity to the instant SEQ ID NO: 29. Therefore, the genus of nucleic acids encompassed by the claims is extremely large, and its members inherently a high degree of variability in terms of their structural and functional properties.

Claim 192 is drawn to an isolated nucleic acid encoding a fluorescent protein and having a sequence comprising any combination of segments described in Figure 15 whose overhangs can anneal to each other. The number of different nucleic acid molecules that can be synthesized from the segments shown in Figure 15 is simply incalculable, and each of these different nucleic acids inherently encodes a protein whose functional properties can only be determined upon nucleic acid synthesis, protein expression, purification, and analysis. Thus, claim 192 also encompasses a very large genus of nucleic acids.

Regarding genus claims, section 2163 of the MPEP states, “For each claim drawn to a genus: The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or

disclosed correlation between structure and function, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

“A “representative number of species” means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004)(“[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species, because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). “A patentee will not be deemed to have invented invention of any species other than the one disclosed.” In re *Curtis*, 354 F3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004)”

In this case, the specification discloses SEQ ID NO: 29 and further teaches that this nucleic acid encodes a fluorescent protein (see page 38). Applicant further discloses related nucleic acid sequences (for example, SEQ ID NO: 1-197 (odd SEQ IDs only)), but these nucleic acids only constitute a small subset of the enormous number of nucleic acids falling within the claimed genus. Furthermore, Applicant does not demonstrate that all of the disclosed nucleic acids share a common function, specifically the encoding of a fluorescent protein (see pages 123-127, where only a subset of proteins encoded by the disclosed nucleic acids were studied). This

limited disclosure does not satisfy the requirement to disclose a representative number of species within the claimed genus. Therefore, it must be concluded that Applicant was not in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 112, 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 218 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites the limitation "the stringent conditions" in line 6. There is insufficient antecedent basis for this limitation in the claim. There is sufficient antecedent basis for "the high stringency conditions".

Claim 218 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: steps (c) and (d) in the process recited in claim 217. Claim 217 is drawn to a nucleic acid made by a process comprising steps (a) and (b). Claim 218, which depends from claim 217, recites that the process further includes step (e), but makes no mention of steps (c) and (d). Accordingly, claim 218 is indefinite.

Allowable Subject Matter

6. Claim 189 is allowed.

Claims 206 and 207 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

7. Applicant's arguments, filed on November 7, 2007, with respect to the rejection of claims 1, 14, 15, 29, 33, 35, 40, 43-45, 48, 49, 87, 188, 192, 203-205, 217, 218, and 225-228 under 35 U.S.C. 112, first paragraph (written description), have been fully considered, but they were not found persuasive. Applicant argues that the disclosure teaches a representative number of species within the claimed genus and refers to the analysis of the proteins encoded by the disclosed nucleic acids (see pages 18-20 of the response). This argument was not found persuasive, because as discussed above, the claimed genus encompasses hundreds of millions of structurally distinct nucleic acids, each of which encodes a different polypeptide. It is extremely unlikely that the functional properties observed for the proteins encoded by the disclosed nucleic acids can be extrapolated to any and all members of the enormous claimed genus. As discussed above, the disclosed species must be representative of the entire genus and reflect the variation within the genus. The small number of nucleic acids disclosed in the specification cannot adequately address the variability in a genus comprising hundreds of millions of structurally and functionally different molecules. See also *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004), which states, "[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those

specifically enumerated.” Likewise, the Federal Circuit determined in *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) that “A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.”

In this case, as discussed above, the likelihood that the results regarding the functional properties of the disclosed nucleic acids and proteins could be extrapolated to any other polynucleotide in the claimed genus is extremely small. It is well known in the art that the structural and functional consequences of mutation(s) in protein-encoding nucleic acids must be determined experimentally, since they are often highly unpredictable. This is especially relevant to the instantly claimed genus, because the ability of a given polynucleotide variant of SEQ ID NO: 29 to encode a functional fluorescent protein is highly unpredictable and depends on the location of the mutation, the identity of the mutation, and its effect on the folded structure of the resulting protein. Thus, it is clear that the small number of species disclosed in the instant application do not constitute a representative number of species within the very large claimed genus, and the rejection under § 112, first paragraph has been maintained.

Applicant’s arguments, see pages 20-25, filed on November 7, 2007, were found persuasive with respect to the following rejections: (1) the rejection of claims 1, 14, 29, 33, 35, 188, and 192 under 35 U.S.C. 102(a) as being anticipated by Lesser, (2) the rejection of claims 1, 15, 29, 33, 35, 40, 43-45, 48, 49, 87, 188, 192, and 225-228 under 35 U.S.C. 102(b) as being anticipated by Lukyanov, (3) the rejection of claims 1, 15, 29, 35, 40, 43-45, 48, 49, 188, and 192 under 35 U.S.C. 102(b) as being anticipated by Tsien, and (4) the rejection of claims 217

and 218 under 35 U.S.C. 103(a) as being unpatentable over Lukyanov in view of Short.

Applicant's amendments to the claims overcome these rejections, and therefore, they have been withdrawn.

Conclusion

8. Claim 189 is allowed. Claims 206 and 207 have been objected to as being dependent on a rejected base claim. As noted above in section 6, claims 206 and 207 would be allowable if they were rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1, 14, 15, 29, 33, 35, 40, 43-45, 48, 49, 87, 188, 192, 203-205, 217, 218, and 225-228 have been rejected. The rejected claims are free of the art but have been rejected for other reasons, specifically failure to comply with the written description requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela Bertagna whose telephone number is 571-272-8291. The examiner can normally be reached on M-F, 7:30 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMB
Amb

/Cynthia Wilder/
Patent Examiner
Art Unit 1637